

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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	:	
FRANCIS FENWICK, EDWARD SAFRAN, STEVE	:	Civil Action No.:
HARDING, MARY WARDRETT, AND LINDA YOUNG,	:	3:12-cv-07354-PGS-DEA
Individually and on behalf of all others similarly situated,	:	
	:	Honorable Judge Peter G. Sheridan
Plaintiffs,	:	
	:	
vs.	:	<b>JOINT PROPOSED DISCOVERY PLAN</b>
	:	
RANBAXY PHARMACEUTICALS, INC., RANBAXY	:	<b>INITIAL SCHEDULING</b>
LABORATORIES, LTD., RANBAXY LABORATORIES,	:	<b>CONFERENCE</b>
INC., RANBAXY, INC., RANBAXY USA, OHM	:	
LABORATORIES, ABC CORPORATIONS 1-10,	:	
AND JOHN DOES 1-10,	:	
	:	
Defendants.	:	
	X	

1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.

- A) Plaintiffs' Counsel: Barry J. Gainey, Esq.  
Gainey McKenna & Egleston  
95 Route 17 South, Suite 310  
Paramus, New Jersey 07652  
(T) 201-225-9001  
(F) 201-225-9002
- B) Defendants' Counsel: Michael E. Patunas, Esq.  
Mayra V. Tarantino, Esq.  
Patunas Tarantino LLC  
24 Commerce Street, Suite 606  
Newark, New Jersey 07102  
(T) 973-396-8740  
(F) 973-396-8743  
mpatunas@patunaslaw.com  
mtarantino@patunaslaw.com

Jay P. Lefkowitz, Esq. (*pro hac vice*)  
Devora W. Allon, Esq. (*pro hac vice*)  
Dmitriy Tishyevich, Esq. (*pro hac vice*)  
Kirkland & Ellis LLP  
601 Lexington Avenue  
New York, New York 10022  
jay.lefkowitz@kirkland.com  
devora.allon@kirkland.com  
dmitriy.tishyevich@kirkland.com

2. Set forth a brief description of the case, including the causes of action and defenses asserted.

### **Plaintiffs' Position**

This case is a class action on behalf of consumers who purchased a prescription drug called Atorvastatin, which is a generic version of Lipitor. The prescription pills in question were manufactured and sold by the Ranbaxy defendants.

In November of 2012, there was an FDA recall of 41 lots of Ranbaxy's Atorvastatin pills because they were contaminated with glass particles. The recall was only at the retail level. Consumers who purchased the contaminated pills did not receive refunds. The defendants have not stated publicly how many pills were involved but a Wall Street Journal article indicated that the 41 lots consisted of at least 480,000 bottles of the contaminated pills.

The plaintiffs are seeking damages for breach of warranty and other claims, including the retail value of uncontaminated pills, a refund, or replacement products as well as other relief. The plaintiffs' Complaint contains five counts, four of which are for breach of warranty (implied and express). The fifth count is for unjust enrichment. All five counts survived the defendants' motion to dismiss. Judge Sheridan's Decision and Opinion states that the Ranbaxy pills were not as safe as the Lipitor pills for which they are a generic version. He also stated that the contaminated pills were "below commercial standards". As he put it, this is a "simple refund case".

The defendants' defenses that the plaintiffs' claims are preempted by the federal Food Drug and Cosmetics Act and are barred by the New Jersey Products Liability Act were rejected by Judge Sheridan in his Decision and Order on the Motion to Dismiss, which is now law of the case. As such, those defenses can no longer be asserted.

### **Defendants' Position**

The defendants deny allegations as to liability and as to the class action of the Third Amended Complaint. Defendants have also asserted numerous defenses, including that plaintiffs' claims are preempted by the federal Food Drug and Cosmetics Act, and are barred by the New Jersey Products Liability Act.

In November 2012, Ranbaxy initiated a voluntary recall of certain lots of the Atorvastatin Calcium Tablets (the "Product") in consultation with the FDA. Because the recall was classified as "Class II" under FDA regulations, it was conducted at the retail level; that is, the Product was recalled from retailers but not consumers. Recognizing the *de minimis* nature of any foreign content in the

recalled Product, the FDA stated that “[t]he possibility of adverse health problems related to the recalled atorvastatin is extremely low,” and advised consumers that they should continue taking the medication without interruption unless otherwise directed by a health care provider. Defendants deny that certain recalled lots of the Product did not meet the warranty of merchantability, and state that the Product was merchantable. Defendants further deny that they breached any express warranty related to the Product, or that plaintiffs have even identified an express warranty that defendants supposedly breached. Finally, defendants also deny that they were unjustly enriched at plaintiffs’ expense.

3. Have settlement discussions taken place? Yes  X  No \_\_\_\_.

### **Plaintiffs’ Position**

At the Court Conference held on November 17, 2015, the parties agreed to have the case stayed and administratively terminated so that they could engage in settlement discussions. The defendants had previously refused to discuss settlement but suddenly requested a settlement demand just before the Court Conference.

In order to provide an informed settlement demand, the plaintiff requested certain information from the defendants. The defendants provided a very limited response. The defendants refused to give the plaintiff some very basic case information, such as identities of the 36 “customers” to whom Ranbaxy shipped the 41 lots of contaminated pills (Ranbaxy described them as wholesalers and chains). It is plaintiff’s position that the names must be disclosed immediately as part of the initial disclosure by the parties. The defendants have refused to provide the basic information but have not provided a legitimate reason. On March 10<sup>th</sup>, they indicated for the first time that they do not believe that the identities of the 36 customers to whom Ranbaxy shipped the 41 lots must be included as part of their initial disclosure. (As noted below, the plaintiffs believe that the identities of the 36 customers must be disclosed as witness information under Rule 26(a)(1).)

Nonetheless, the plaintiff worked with a consultant/expert to prepare a damages preview model. Because of the defendants’ stonewalling, average retail prices were used rather than the retail prices for the specific retailers where the pills were distributed. Some preliminary research was done concerning pharmacy sales and some assumptions were made using market share information. Using the average retail price at the top 10 U.S. pharmacy retailers, the estimated total retail value of the 80,224 non-returned bottles was calculated as being \$21.2 Million. Therefore, the plaintiff’s settlement demand was \$21.2 Million. When Ranbaxy provides more information, including the names of the 36 customers who received the contaminated pills, the plaintiff can calculate the damages for the class more accurately, using case specific information rather than making assumptions using approximate market shares and averages.

In addition to the monetary damages, the settlement demand included injunctive relief, which was Ranbaxy agreeing that they will not place the contaminated pills back in the public market or otherwise recycle or reprocess them into other pills. An alternative was offered for Ranbaxy to simply destroy the contaminated pills.

A month and a half after plaintiff gave the defendants the settlement demand, the defendants responded. The defendants unilaterally ended settlement talks without ever making an offer or even providing feedback on the 4 page settlement demand letter. Quite frankly, it was astonishing. Plaintiff’s counsel reached out to defense counsel to continue settlement discussions but to no avail.

**Defendants' Position**

Defendants strongly disagree with plaintiffs' characterizations of the parties' discussions and object to plaintiffs' violation of both the letter and spirit of the settlement privilege by providing this Court with a misleading and incomplete recitation of data shared in the course of confidential settlement discussions.

Plaintiffs asked defendants to provide various information to facilitate discussion between the parties. While defendants were under no obligation to provide any of this information, defendants nonetheless provided all data that was reasonably necessary for its requested purpose. Defendants did not provide information that was irrelevant to the dispute and/or beyond the scope of the parties' discussions. At plaintiffs' request, defendants even provided additional information when plaintiffs made a follow-up request to defendants three weeks after receiving defendants' initial data production.

Three weeks thereafter, plaintiffs demanded \$21.2 million (in addition to injunctive relief and attorneys' fees and costs) to settle this lawsuit. That figure bears no relationship whatsoever with any measure of damages actually suffered by the putative class under any cognizable legal theory. Nor does it account for the controlling law in this Circuit and elsewhere, which defendants believe precludes the named plaintiffs from collecting damages and/or certifying a class in this matter should this litigation proceed to discovery.

In light of plaintiffs' unreasonable settlement position, it became clear to defendants that further discussions or a mediation would not be productive. Accordingly, these discussions were terminated. Defendants are open to the possibility of engaging in further discussions with the plaintiffs in the future when and if they provide a reasonable demand.

(a) What was plaintiffs' last demand?

(1) Monetary demand: \$21.2 Million

(2) Non-monetary demand: Injunctive relief of Ranbaxy agreeing that they will not place the contaminated pills back in the public market or otherwise recycle or reprocess them into other pills. An alternative was offered for Ranbaxy to simply destroy the contaminated pills.

(b) What was defendant's last offer?

(1) Monetary offer: No offer to date.

(2) Non-monetary offer: No offer to date.

4. The parties [have  X  have not       ] met pursuant to Fed. R. Civ. P. 26(f).

5. The parties [have \_\_\_\_ have not  X  ] exchanged the information required by Fed. R. Civ. P. 26(f). If not, state the reason therefore.

The parties will exchange initial disclosures by March 25, 2016.

6. Explain any problems in connection with completing the disclosures required by Fed. R. Civ. P. 26(a)(1).

**Plaintiffs' Position.**

The defendants have refused to provide basic, discoverable information about the case, which should be exchanged under Rule 26(a)(1). In particular, Rule 26(a)(1) requires the disclosure of witness information along with the subject of the information that those witnesses have relating to the case. For the first time on March 10<sup>th</sup>, the defendants stated their position that the identities of the 36 "customers" to whom Ranbaxy shipped the 41 lots of contaminated pills (Ranbaxy described them as wholesalers and chains) "goes well beyond disclosures required by Rule 26(a)(1)" Their position is unsupported. The 36 "customers" to whom the contaminated pills were shipped are obviously witnesses and the information must be disclosed pursuant to Rule 26(a)(1). The plaintiffs should not have to wait until formal discovery requests are served as the defendants argue below. That is a waste of time and it is contrary to the Federal Rules.

**Defendants' Position.**

Defendants will provide their Rule 26(a)(1) disclosures to plaintiffs, which will include the information that needs to be disclosed under that rule. Plaintiffs' request for other information (such as, for example, the identities of wholesalers to whom defendants had shipped the product at issue) goes well beyond disclosures required by Rule 26(a)(1). After discovery begins and after plaintiffs have served formal discovery requests, defendants will respond to and/or object to those requests as may be appropriate, in accordance with the scheduling order to be entered and in accordance with defendants' discovery obligations.

7. The parties [have \_\_\_\_ have not  X  ] conducted discovery other than the above disclosures. If so, describe.

**Plaintiffs' Position.**

The defendants have refused to provide basic, discoverable information about the case, which should be exchanged under Rule 26(a)(1). In particular, Rule 26(a)(1) requires the disclosure of witness information along with the subject of the information that those witnesses have relating to the case. For the first time on March 10<sup>th</sup>, the defendants stated their position that the identities of the 36 "customers" to whom Ranbaxy shipped the 41 lots of contaminated pills (Ranbaxy described them as wholesalers and chains) "goes well beyond disclosures required by Rule 26(a)(1)" Their position is unsupported. The 36 "customers" to whom the contaminated pills were shipped are obviously witnesses and the information must be disclosed pursuant to Rule 26(a)(1). The plaintiffs should not have to wait until formal discovery requests are served as the defendants argue below. That is a waste of time and it is contrary to the Federal Rules.



**Defendants' Position.**

Defendants will provide their Rule 26(a)(1) disclosures to plaintiffs, which will include the information that needs to be disclosed under that rule. Plaintiffs' request for other information (such as, for example, the identities of wholesalers to whom defendants had shipped the product at issue) goes well beyond disclosures required by Rule 26(a)(1). After discovery begins and after plaintiffs have served formal discovery requests, defendants will respond to and/or object to those requests as may be appropriate, in accordance with the scheduling order to be entered and in accordance with defendants' discovery obligations.

8. Proposed joint discovery plan:

- (a) Discovery is needed on the following subjects:

**Plaintiffs' Position.**

The plaintiffs want discovery relating to the contaminated pills in question and the related recall, including the items listed below in 8(a)(1) through 8(a)(13). As noted above, the defendants have refused to provide basic, discoverable information about the case as part of their initial disclosure. The problem should be addressed at the Initial Conference before Magistrate Judge Arpert.

Pursuant to Local Rule 26.1(b)(2)(d), the plaintiffs have noted that they will request computer-based or other digital information from the defendants, including that related to the discovery issues noted below. The proposed schedule in number 8(c) below includes a date for an e-discovery conference after the parties make their Rule 26 disclosures.

- (1) Information, documents, and records about the number of contaminated pills and bottles of pills that the defendants sent out to retailers (i.e., pharmacies, etc.).
- (2) Information, documents, and records about the number of pills and bottles that were returned as a result of the retail-only recall.
- (3) Information, documents, and records about the identities and contact information for all of the retailers (i.e., pharmacies, etc.) to whom the defendants sent the contaminated pills.
- (4) Specific information about the number of pills and bottles sent to each retailer including the lot numbers and the NDC numbers that corresponds to those bottles and the pack size of the bottles.
- (4) Information, documents, and records about whether defendants provided any contaminated pills and bottles to consumers or anyone else other than the retailers noted above.
- (5) Information, documents, and records about details of the distribution of the pills and bottles, including who, when, where, and how much.

- (6) Information, documents, and records about details of the recall of the pills and bottles, including number of pills and bottles recalled, the number returned, what was done with those pills and bottles and the current whereabouts.
- (7) Information, documents, and records about whether the defendants have any information about the consumers who purchased the contaminated pills? If so, that information is needed.
- (8) Information, documents, and records about the records and electronically stored information that the defendants have and the location, format, etc. of that information.
- (9) What tracking information and system is available for tracking the contaminated pills.
- (10) Information, documents, and records about the FDA recall.
- (11) Information about the retail value of the pills if they were not contaminated, including for each of the different bottle sizes and dosages involved in the 41 recalled lots.
- (12) Information about the identities of the 36 “customers” to whom Ranbaxy shipped the 41 lots of contaminated pills (Ranbaxy described them as wholesalers and chains) and detailed information about the specific pills sent to each “customer”.
- (13) Information about the retail value and price of the pills if they were not contaminated, including for each of the different bottle sizes and dosages involved in the 41 recalled lots.

**Defendants’ Position.**

The defendants intend to seek discovery, including computer-based or other digital information as may be applicable (see L.R. 26.1(b)(2)(d)), on at least the following topics (with class discovery and merits discovery to proceed in staggered phases, as detailed further below):

- (1) Plaintiffs’ allegations that this matter is appropriate for treatment as a class action.
- (2) Plaintiffs’ alleged purchases of the Product, including all prescriptions, receipts and other documentation of those purchases.
- (3) The amounts allegedly paid by plaintiffs for the Product, including evidence of any insurance, copays, deductibles and insurance coverage of said purchases.
- (4) Whether plaintiffs actually suffered any cognizable loss due to their purchase of the Product, and any documents and information supporting plaintiffs’ damages contentions.
- (5) Plaintiffs’ alleged efforts to return the Product.

(6) All of the defenses asserted in defendants' Answer to the Third Amended Complaint.

At this time, defendants take no position on whether the categories of discovery plaintiffs intend to seek are appropriate, and defendants reserve all rights. After discovery begins and after plaintiffs have served formal discovery requests, defendants will respond to and/or object to those requests as may be appropriate, in accordance with the scheduling order to be entered and in accordance with defendants' discovery obligations.

(b) Discovery [should   X   should not       ] be conducted in phases or be limited to particular issues. Explain.

The parties agree to conduct fact and expert discovery in two separate phases as follows. The parties will first conduct fact and expert discovery on whether class certification is appropriate under Fed. R. Civ. P. 23 ("class discovery"). This initial phase of discovery will not include any discovery on the merits of plaintiffs' claims ("merits discovery"). Following completion of class discovery, plaintiffs will file a motion for class certification as contemplated by the proposed schedule below. In the event the Court grants that motion and certifies the class, the parties will, within thirty days of the Court's order (or, if any party appeals such an order under Fed. R. Civ. P. 23(f), within thirty days of the ultimate disposition of such an appeal) jointly propose a schedule for merits discovery and any other remaining pre-trial deadlines.

(c) Proposed schedule:

- (1) Fed. R. Civ. P. 26 Disclosures by March 25, 2016.
- (2) E-Discovery conference pursuant to L. Civ. R. 26.1(d) on or before April 20, 2016.
- (3) Service of initial written discovery on class discovery issues by May 20, 2016.
- (4) 25 Interrogatories by each party to each other party.
- (5) 10 depositions to be taken by each party. However, plaintiffs may need additional non-party depositions. That will be determined by the information that is received during discovery. The other depositions that may be necessary will relate to information about the retailers to whom the defendants sent the contaminated pills. They will also relate to information about the tracking methods that are available to track the contaminated pills.
- (6) Motions to amend or to add parties to be filed by August 15, 2016.
- (7) Factual discovery on class certification to be completed by December 22, 2016.
- (8) Plaintiffs' expert report on class certification due on March 10, 2017.
- (9) Defendants' expert report on class certification due on April 21, 2017.
- (10) Expert depositions on class certification to be completed by June 9, 2017.



- (11) The parties will file *Daubert* / Fed. R. Evid. 702 motions on class certification expert issues (if any) by August 18, 2017; with any opposition to such motions to be filed by September 19, 2017; and any replies to be filed by October 6, 2017.

Plaintiffs will then file a motion for class certification (if any) after the Court has ruled on all *Daubert* / Fed. R. Evid. 702 motions on class certification expert issues with the briefing schedule to be determined at that time.

- (12) In the event the Court grants plaintiffs' motion for class certification, the parties will, within thirty days of that order (or, if any party appeals such an order under Fed. R. Civ. P. 23(f), within thirty days of the ultimate disposition of such an appeal) jointly propose a schedule for merits discovery and any other remaining pre-trial deadlines.

- (d) Set forth any special discovery mechanism or procedure requested.

As noted above, plaintiffs anticipate needing non-party discovery from the 36 "customers" to whom the defendants shipped the contaminated pills and/or from retailers and/or others. A streamlined mechanism and/or procedure would be most efficient and details will be discussed.

- (e) A pretrial conference may take place on a date to be determined, per the Court's availability.

- (f) Trial date: To be determined, per the Court's availability. (☒ Jury Trial; ☐ Non-Jury Trial).

9. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problems with out-of-state witnesses or documents, etc.)? Yes ☐ No ☒.

10. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced? Yes ☐ No ☒.

None to date.

11. Do you anticipate entry of a Discovery Confidentiality Order? See L. Civ. R. 5.3(b) and Appendix S.

Yes.

12. Do you anticipate any discovery problem(s) not listed above? Describe. Yes ☐ No ☒.

None to date.

13. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.).

**Plaintiffs' Position**

As discussed above, the plaintiff worked with a consultant/expert to prepare a settlement demand letter. The four page settlement demand letter provided specific detail on the basis for the settlement demand. The defendants did not respond with an offer.

It is the plaintiff's position that the case is appropriate for mediation and should be referred to mediation. The plaintiff would prefer to work with a private mediator but is open to this matter being referred to the Court Mediation Program.

**Defendants' Position**

As detailed in more detail in Section 3 above, the parties have discussed the possibility of settlement. Defendants have carefully considered plaintiffs' settlement demand, but given the parties' significant disagreement over the settlement valuation of this case, defendants do not believe that proceeding to ADR will be productive at this time. Defendants are open to the possibility of revisiting this issue in the future, in the event the settlement posture of this case were to change meaningfully.

14. Is this case appropriate for bifurcation? Yes \_\_\_\_ No X.

No, except that the parties agree to resolve class certification issues before proceeding to the merits of plaintiffs' claims, as set forth above.

15. An interim status/settlement conference (with clients in attendance) should be held in June 2016.

16. We [do \_\_\_\_ do not X] consent to the trial being conducted by a Magistrate Judge.

17. Identify any other issues to address at the Rule 16 Scheduling Conference. [ ]

/s/ Barry J. Gainey, Esq.  
GAINNEY McKENNA & EGGLESTON  
Barry J. Gainey, Esq.  
March 11, 2016

/s/ Michael E. Patunas, Esq.  
PATUNAS TARANTINO LLC  
Michael E. Patunas, Esq.  
Mayra V. Tarantino, Esq.  
March 11, 2016